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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/036,819	03/09/98	SHAMI	A 107-145D-C

JOSEPH E MUETH  
8TH FLOOR  
225 SOUTH LAKE AVENUE  
PASADENA CA 91101

HM11/0904

EXAMINER	
DEVI, S	
ART UNIT	PAPER NUMBER
1645	16
DATE MAILED: 09/04/01	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/036,819

Applicant(s)

El Shami

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 5, 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 54 is/~~are~~ pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/~~are~~ withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/~~are~~ allowed.
- 6) ☒ Claim(s) 54 is/~~are~~ rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/~~are~~ objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/~~are~~ objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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### **DETAILED ACTION**

#### **Change of Art Unit Location**

1) Effective 20 June 2000, the Art Unit location of the instant application in the US PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1645.

#### **Applicant's Amendment**

2) Acknowledgment is made of Applicant's amendment filed 06/05/00 (paper no. 13) is response to the noon-final Office Action mailed 12/02/99 (paper no. 12).

#### **Status of Claims**

3) Claims 42-53 have been canceled via the amendment filed 06/05/00 (paper no. 13).  
New claim 54 has been added via the amendment filed 06/05/00 (paper no. 13).  
Claim 54 is pending in this application and is under examination.

#### **Prior Citation of Title 35 Sections**

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

#### **Prior Citation of References**

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

#### **Specification - Objection Maintained**

6) The objection to the specification made in paragraph 5(b) of the Office Action mailed 02/04/99 (paper no. 4) and maintained in paragraph 8 of the final Office Action mailed 06/24/99 (paper no. 6) is maintained for reasons set forth therein. Although Applicant has replaced Tables 20-25 via the amendment filed 04/12/99 (paper no. 5), the rest of the Tables and related text have not been amended. However, Applicant assures the Office that the specification would be appropriately edited upon indication of allowance.

#### **New Rejection(s)**

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7) Applicant is asked to note the new rejections made in this Office Action. Applicant's amendment necessitated the new grounds of rejections presented in this Office Action.

**Rejection under 35 U.S.C. 112, First paragraph**

8) Claim 54 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 54 includes following newly added limitations as shown below in bold:

54. A method for determining the concentration of a free **portion of testosterone** ligand in a biological fluid, wherein said free testosterone is in equilibrium with **another portion of the testosterone** bound to one or more endogenous binders in said fluid comprising the steps of (a) forming a mixture of a sample of said fluid with (1) an amount of a specific antibody for the free testosterone insufficient to substantially affect said equilibrium, and (2) **a labeled derivative of testosterone** which is radioiodinated 6-hydroxy-testosterone-19-carboxymethyl ether histamine that binds to said antibody and has affinity for the endogenous binders lower than that of testosterone for said endogenous binders, (b) maintained said mixture to permit **said labeled derivative to complete** with the free testosterone for binding with the antibody, (c) measuring the amount of **said labeled derivative** that has, or has not, become bound to the antibody, and (d) determining the concentration of free testosterone from said measurement, **wherein the improvement comprises including in the mixture an amount of a blocking agent which is sulfobromophthalein which substantially reduces the binding of said labeled derivative to the endogenous binders without substantially reducing the binding of testosterone to said endogenous binders.**

However, there appears to be no descriptive support in the instant specification for these added limitations. Applicant points to Example 1 on pages 25 and 26 and Example 2 on pages 26 and 27 as providing support for the new claim 54. However, this part of the specification does not support all the limitations or steps included in the claimed method. The specification does not appear to include several limitations of claim 54, especially, for example, "labeled derivative of testosterone"; "wherein the improvement comprises including in the mixture an amount of a blocking agent which is sulfobromophthalein which substantially reduces the binding of said labeled derivative to the endogenous binders without substantially reducing the binding of testosterone to said endogenous binders". Therefore, the new limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a

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method. See M.P.E.P. 608.04 to 608.04(c).

Applicant is respectfully requested to point to the descriptive support in specific part(s) of the disclosure as filed, for the newly added limitations, or to remove the new matter from the claim.

**Rejection(s) under 35 U.S.C § 112, Second Paragraph**

9) Claim 54 is rejected under 35 U.S.C §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 54 is vague and indefinite in the recitation: "derivative of testosterone" (see lines 6, 9, 10, 11 and 14), because it is unclear what is encompassed in this recitation. It is unclear what properties should a substance have in order to qualify as a "derivative of testosterone". Absent a precise definition for the term "derivative", the metes and bounds of the claim cannot be envisaged.

(b) Claim 54 lacks antecedent basis for the recitation: "said free testosterone" (see line 2), because there is an earlier recitation of "a free portion of testosterone" in the claim (see line 1), but not of "free testosterone".

(c) Claim 54 is vague and indefinite in the recitations: "substantially affect" (see line 5); "substantially reduces" (see line 14) and "substantially reducing" (see line 15), because it is unclear what degree of "affecting" and "reducing" is encompassed in the term "substantially affect", "substantially reduces" and "substantially reducing".

**Objection**

10) Claim 54 is objected to for the incorrect recitations "'derivative to **complete** with the free testosterone" and "comprising the steps of (a) forming ..... (b) maintained...." [Emphasis added]. It is suggested that Applicant replace the recitation "complete" with --compete--, if this is what Applicant means, and the recitation "maintained" with --maintaining--.

**Remarks**

11) Claim 54 stands rejected.

12) Papers related to this application may be submitted to Group 1600, AU 1641 by facsimile

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transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242.


13) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
S. Devi, Ph.D.  
Primary Examiner  
August 2001